MICHAEL B. ENZI, WYOMING, CHAIRMAN

JUDD GREGG, NEW HAMPSHIRE BILL FRIST, TENNESSEE LAMAR ALEXANDER, TENNESSEE RICHARD BURR, NORTH CAROLINA JOHNNY ISAKSON, GEORGIA MIKE DEWINE, OHIO JOHN ENSIGN, NEVADA ORRIN G. HATCH, UTAH JEFF SESSIONS, ALABAMA PAT ROBERTS. KANSAS EDWARD M. KENNEDY, MASSACHUSETTS CHRISTOPHER J. DODD, CONNECTICUT TOM HARKIN, IOWA BARBARA A. MIKULSKI, MARYLAND JAMES M. JEFFORDS (II), VERMONT JEFF BINGAMAN, NEW MEXICO PATTY MURRAY, WASHINGTON JACK REED, RHODE ISLAND HILLARY RODHAM CLINTON, NEW YORK

United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

WASHINGTON, DC 20510-6300

KATHERINE BRUNETT McGUIRE, STAFF DIRECTOR

J. MICHAEL MYERS, MINORITY STAFF DIRECTOR AND CHIEF COUNSEL

http://help.senate.gov

May 20, 2005

Lester M. Crawford, D.V.M., Ph.D. Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Crawford:

I am writing to inquire about the FDA's plans to ensure the proper labeling of sweeteners on soft drinks. This letter follows on my previous letter of June 2, 2004, regarding the use of "and/or" labeling (e.g., "high fructose corn syrup and/or sugar).

I was pleased to see that, on November 26, 2004, the Food and Drug Administration (FDA) withdrew consideration of the National Soft Drink Association's 1994 petition requesting a special exemption of FDA regulation to allow soft drink manufacturers to use "and/or" labeling of sweeteners on soft drink labels (69 Federal Register 6833). In its November ruling, FDA noted that

in the preamble in its proposed rule (58 Federal Register 2953) that its final decision on whether to revise its regulations to permit "and/or" labeling for sweeteners in soft drinks would be based largely on whether comments in response to the proposed rule included data demonstrating that it is impracticable to produce the limited number of versions of a label that would be necessary if "and/or" labeling were not permitted.

The agency received no such data and therefore did not have sufficient basis to proceed to a final rule allowing "and/or" labeling for soft drinks. Accordingly, this comment does not persuade the agency to reconsider the withdrawal of this proposed rule.

Further, the agency also acknowledged "that it has not pursued any enforcement action against soft drink manufacturers who are using 'and/or' labeling because of the pending rulemaking," and that the agency "is considering its position on the use of 'and/or' labeling."

Lester M. Crawford May 20, 2005 Page 2

As I stated in my previous letter on this issue, I am concerned that the continued use of "and/or" sweetener declarations in soft drink labeling misleads consumers about the contents of these products.

Due to advances in packaging technology and the rapid turnover of soft drink can inventories, compliance with this labeling regulation should not create a logistical or financial challenge for soft drink manufacturers.

I request that you advise me as to FDA's plans to ensure proper labeling of soft drinks in the wake of the agency's withdrawal of the proposed rule. Specifically, I would like to know what enforcement authority you intend to exercise to ensure proper labeling, and your timeframe for commencing enforcement activities.

Thank you for prompt attention to this important matter.

Sincerely

Michael B. Enzi

United States Senator

MBE:mmd